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August 21, 2001

Dr. Edward L. Baker
Centers for Disease Control and Prevention
Executive Secretary, Clinical Laboratory Improvement Advisory Committee
Director, Public Health Practice Program
Williams Building
3877 Brandywine Road
Atlanta, GA 30333

Dear Dr. Baker:

The College of American Pathologists (CAP) wishes to bring a concern to the Clinical Laboratory Improvement Advisory Committee (CLIAC) regarding the treatment of private accreditation organizations under the recently finalized Health Insurance Portability and Accountability Act privacy rules. Specifically, private accreditation programs, such as the College's Laboratory Accreditation Program, are treated as a "business associate" rather than a "healthcare oversight agency" with respect to the laboratory accreditation activities provided on behalf of the Centers for Medicare and Medicaid Services (CMS) in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The issue is of importance at this time, because the Department of Health and Human Services (DHHS) is currently drafting modifications to the final privacy rule.

The College fully supports efforts to protect the confidentiality of patients' medical records, but is concerned that the interpretation of the "business associate" definition will impose unintended and unnecessary regulatory burdens on laboratory accreditation operations. As currently drafted, the final regulations would require private accreditation programs to enter into "business associate" agreements with laboratories in order to perform the inspection and accreditation activities required under CLIA. Under the final regulations, all private accreditation organizations would be required to execute a "business associate" agreement with each of the more than 17,000 laboratories accredited - even though the accreditation inspection does not directly involve the obtaining of patient medical information. Securing such agreements would involve significant costs (estimated at $34 million[1]) and increased administrative burdens - all of which could be passed onto consumers without significantly improving the privacy of patient information or laboratory quality.

[1] 17,000 "certificate of accreditation" tabs, 10 hours of legal consultation and negotiation her lab, $200/hour legal fee = $34 million

The privacy regulations do provide that "health oversight agencies," such as CMS, are not subject to the "business associate" requirement. In CAP's view, a laboratory accreditation performed by a private organization under the authority of CMS and federal statute, should be considered a health oversight activity and not be subject to business associate agreements.

In sum, CAP believes that the "business associate" requirements should not apply to private accreditation activity. In carrying out the directives of CMS under CLIA this program -functions as a "health oversight agency" and should be considered as such under any final rule.

The College greatly appreciates CLIAL's consideration of this important matter and CLIAC's support in raising it as a concern to HHS. We are available to discuss any questions with you at your convenience. In that regard, please contact me or David Mongillo in the College's Washington office at 202 354-7110. A copy of the CAP comments submitted to the DHHS is attached for your information.

Sincerely,

/S/ Paul Bachner, MD, FCAP
President